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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,063	DAVENPORT ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/23/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-38,40-48 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-38,40-48 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24, 39, 49 and 51 have been cancelled. Claims 25-38, 40-48, and 50 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 4/23/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-38 and 40-48 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 recites between about 95% to about 100 % by weight whey powder and between about 1% and about 5 % weight lactase. It is unclear in the case when the composition is 100% by weight whey powder than lactase can not be present but yet it is positively recited. Correction is required. The claims will be examined as they read on an amount less than100% whey powder.

Response to arguments:

Applicant did not address this rejection and therefore it is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 26, 33, 38, 40-42, 44, 46, and 50 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (US 4522832).

Applicant claims: 1) A method for reducing energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components; wherein the composition comprises a protein component comprising whey powder and lactase in the following approximate effective proportions: between about 95% to about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase; and 2) A method for providing critical care to a mammal

with an energy deficiency by reducing the energy deficiency in the mammal comprising the step of administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Morrison teaches in Column 5, Example 1 reproduced below:

EXAMPLE I

An enriched bread was produced via a zero bulk fermentation procedure using the following formulations:

COMMERCIAL FORMULA: FORMULA	ENRICHED WHITE BREAD STANDARD	STANDARD WITH REDUCED SUGAR	IN-VENTION
ENRICHED WHITE FLOUR	100	100	100
SUGAR	4	2	2
SHORTENING	3	3	3
SALT	2	2	2
WHEY POWDER	4	4	4
YEAST	3.25	3.25	3.25
[1]EMULSIFIER	0.25	0.25	0.25
WATER	65	65	65
[2]LACTASE	—	—	6.8

All values are in lbs. except * which is in grams.
[1]ATMUL 500 obtained from the Atlas Chemical Company
[2]Food grade fungal lactase obtained from *Aspergillus Oryzae* and sold under the trade mark TAKAMINE by the Enzyme Products Division of Miles Laboratories, Inc. having an activity of 14,000 units/gram.

The shortening is fat and is present at less that 3%. Salt is NaCl. Whey powder makes up 100% of the protein component. Lactase is present between about 1 to about 5% and the narrower range of about 2% to about 2.5% by weight and converts lactose to the monosaccharides glucose and galactose (see also column 4, lines 35-47).

Please note that the "enriched white flour" in the Example 1 above was not expressly disclosed as to how it was enriched.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Morrison is that Morrison do not expressly teach a method of reducing energy deficit in and provide critical care for a mammal.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the bread of Morrison to reduce the energy deficit in and provide critical care for a mammal and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the utility of the bread is to be ingested. Anyone ingesting the bread, which reads on enteral administration because it is going to the stomach, would receive all the benefits of the bread including reducing their energy deficit and providing critical care. That is the function of eating food. Food provides calories.

With regards to the size of the whey powder being smaller than about 45 mesh, the mesh size of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in

the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal mesh size each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient mesh size would have been obvious at the time of applicant's invention.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that: "Example I of Morrison is a baking formulation that is processed to form bread. Morrison discloses that during such processing the lactase converts lactose in to the simple sugars glucose and galactose. Morrison does not disclose that the bread formed after such a process comprises about 1% to about 5 % by weight of lactase." Respectfully, the Examiner cannot agree. The lactase must still be present in the product because there is no step to remove the enzyme.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-38, 40-48, and 50 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (US 5902797) in view of Martinez et al. (J Dairy Sci. 1998, 71, 893-900) and The Merck manual of medical information Home Edition Robert Berkow Ed. Published by Merck Research Laboratories Whitehouse Sation, NJ 1997, pages 535-536 and Mahmoud et al. (US 5,104,676) and Hsia (US 6,294,166) and Acosta et al. (US 5550146).

Applicant claims: 1) A method for reducing energy deficit in a mammal comprising the step of enterically administering to the mammal an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components; wherein the composition comprises a protein component

comprising whey powder and lactase in the following approximate effective proportions: between about 95% to about 100 % by weight of whey powder, and between about 1% to about 5 % by weight of lactase; 2) A method for providing critical care to a mammal with an energy deficiency by reducing the energy deficiency in the mammal comprising the step of administering to the mammal a diet consisting of a critical care feeding program that consists of an energy promoting effective amount of a composition having less than 3% fat comprising an effective proportion of components, and 3) A method for maintaining health in a mammal comprising the step of administering to the mammal an effective amount of a composition having less than 3% fat comprising an effective proportion of components; wherein the composition comprises a feed component comprising a non-soluble fiber.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Bell et al. teach **methods of providing nutritional supplementation** to an individual in need thereof comprising administering to the individual a nutritional supplement comprising from about 5 to 25 grams of carbohydrate; from about 1 to about 25 grams of protein and from about 1 to about 10 grams of fat. Therefore, a composition with 24 grams of carbohydrate; 25 grams of protein and 1 gram of fat is fairly taught which would have a total of 50 grams of which 1 gram is fat which is about 2% by weight fat (Abstract and claim 27 but see claims 27-33). The protein can be from **whey powder** which would then make up about 100% of the protein component (claim 29). Carbohydrates includes simple and complex carbohydrates (column 2, lines 52-67 and

column 3, lines 1-40). The nutritional supplement can contain other vitamins, minerals, antioxidants, fiber and other dietary supplements (column 4, lines 34-36). Bell et al. clearly teach in column 4, lines 36-67 and column 5, lines 1-4 reproduced below (Examiner added emphasis):

> The nutritional supplement can also contain other ingredients such as one or a combination of vitamins, minerals, antioxidants, fiber and other dietary supplements. Selection of one or several of these ingredients is a matter of formulation design, consumer preference and end-user. The amount of these ingredients added to the nutritional supplements of this invention are readily known to the skilled artisan and guidance to such amounts can be provided by the U.S. RDA doses for children and adults. Vitamins and minerals that can be added include, but are not limited to, calcium phosphate or acetate, tribasic; potassium phosphate, dibasic; magnesium sulfate or oxide; salt (sodium chloride); potassium chloride or acetate; ascorbic acid; ferric orthophosphate; alpha-tocopheryl acetate; niacinamide; zinc sulfate or oxide; calcium pantothenate; copper gluconate; riboflavin; beta-carotene; pyridoxine hydrochloride; thiamin mononitrate; folic acid; biotin; chromium chloride or picolonate; potassium iodide; sodium selenate; sodium molybdate; phylloquinone; Vitamin D_3; cyanocobalamin; sodium selenite; copper sulfate; Vitamin A; Vitamin B_6 and hydrochloride thereof; Vitamin E; Vitamin E acetate; Vitamin C; inositol; Vitamin B_{12}; potassium iodide.
>
> Flavors, coloring agents, spices, nuts and the like can be incorporated into the product. Flavorings can be in the form of flavored extracts, volatile oils, chocolate flavorings, peanut butter flavoring, cookie crumbs, vanilla or any commercially available flavoring. Examples of useful flavorings include but are not limited to pure anise extract, imitation banana extract, imitation cherry extract, chocolate extract, pure lemon extract, pure orange extract, pure peppermint extract, imitation pineapple extract, imitation rum extract, imitation strawberry extract, or pure vanilla extract; or volatile oils, such as balm oil, bay oil, bergamot oil, cedarwood oil, cherry oil, cinnamon oil, clove oil, or peppermint

oil; peanut butter, chocolate flavoring, vanilla cookie crumb, butterscotch or toffee. In a preferred embodiment, the nutritional supplement contains cocoa or chocolate, because of the appeal of such ingredients to children.

Preservatives and artificial sweeteners are taught by Bell et al. (column 5, lines 11-23). Beverages amongst other forms are taught (column 2, line 24 and column 5, lines 58-64). Bell et al. teach the supplement is for growth and individual who **require increased calories** and/or protein (column 6, lines 5-27). Consuming the composition of Bell et al. reads on enteric administration because it is going to the stomach.

Martinez et al. teach that whey powder has a high amount of lactose (page 893, left column).

The MERCK MANUAL of medical information teaches that certain individuals are lactose intolerant and can suffer from severe diarrhea which may prevent proper absorption of nutrients (pages 535-536 Sugar Intolerance). Lactase can be added to break down the lactose before the individual consumes the lactose containing product (page 536, Treatment).

Hsia teaches a method of improving the health of a mammal comprising orally administrating viable lactobacillus acidophilus bacteria (a probiotic), non-living yeast and protein from whey or soy isolates (Abstract and claim 1). The amount of bacteria ranges from about 0.1 to about 10% of the total mass of the composition (Column 4, lines 53-56). The amount of yeast is from about 2.5% to about 20% of the total mass of the composition (Column 5, lines 1-2). The amount of protein is from about 25% to about 98% of the total mass of the compositions (Column 5, lines 6-16).

Rosenberg et al. teach supplements that can contain bioflavonoids and glucosamine (Abstract and claims 1-19). Mineral amino acid chelates are taught (column 1, lines 59-67).

Mahmound et al. teach using in supplements oat hull fiber which is insoluble fiber and reads on oats (claim 3).

Acosta et al. teach enteral nutritional composition comprising various amino acids such as L-arginine, L-glutamine and carnitine (clam 1).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Bell et al. is that Bell et al. do not expressly teach a method of reducing energy deficit in a mammal using a composition comprising from about 1% to about 5% by weight lactase. This deficiency in Bell et al. is cured by the teachings of Martinez et al. and the Merck Manual.

2. The difference between the instant application and Bell et al. is that Bell et al. do not expressly teach a method of reducing energy deficit in a mammal using a composition comprising mineral amino acid chelates, glucosamine, probiotics, amino acids, oats or insoluble fiber. This deficiency in Bell et al. is cured by the teachings of Mahmoud et al. (US 5,104,676) and Hsia (US 6,294,166) and Acosta et al. (US 5550146) and Rosenberg et al. (US 6579544).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add lactase as suggested by the Merck Manual to the method of Bell et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Martinez et al. teach that whey powder has lactose and the Merck Manual teaches that some people are lactose intolerant and in that case lactase should be added to convert the lactose. Mixing the lactase with the lactose intrinsically produces glucose and galactose. The predictable result is a compostion for use in a method of reducing energy deficit.

With regards to the amount of lactase to add to the composition, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

With regards to the size of the whey powder being smaller than about 45 mesh, the mesh size of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal mesh size each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the

optimization of ingredient mesh size would have been obvious at the time of applicant's invention.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add mineral amino acid chelates, glucosamine, probiotics, amino acids, oats or insoluble fiber or any other supplemental ingredients as suggested by Mahmoud et al. (US 5,104,676) and Hsia (US 6,294,166) and Acosta et al. (US 5550146) and Rosenberg et al. (US 6579544) to the method of Bell et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bell et al. suggest adding other dietary supplements (column 4, line 36) which includes anything that is edible under the sun and the cited art teaches various dietary supplements. The expected result remains the same: the energy deficit of the individual that consumes the composition is reduced, critical care is provided and health is maintained. It is the Examiner's position that a vitamin in a beverage reads on a liquid vitamin because the beverage is liquid. Administering the composition to any mammal intrinsically reduces the energy deficit and provides critical care of the mammal and maintains its health.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary

skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that the Merck manual does not disclose a composition comprising about 1% to about 5% by weight lactase. That is correct. It is nothing more than routine optimization to determine the optimal amount of lactase to add as discussed above in the absence of unexpected results. The unexpected results are absent.

Applicant asserts that instant claim 50 comprises the step of "administering to the mammal a diet consisting of a critical care feeding program" and that is not taught in the references. The Examiner cannot agree. First of all, a mammal cannot be administered a program but rather the mammal is administered the components in the program. In this case, the component is a composition having less than 3% fat comprising an effective proportion of components which limitation is met by the references cited above. Second of all, administration of the composition is intrinsically meeting a feeding program. The composition is supplied/administered to the mammal. That is a program.

Applicant directs the Examiner to the specification about a 6 year old miniature horse with a foal that was administered some nutritional formulation. The horse showed no significant abnormalities upon physical examination 4 weeks after discharge. However, the foal was also weaned from the mother thus decreasing the energy demands on the mare. The question arises if whether the formulation made the mare better or the fact that the foal was no longer nursing and placing energy demands on the mare was the factor.

Applicant's arguments are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst V Arnold
Examiner, Art Unit 1616

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616